DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20, 2015

Stryker Corporation
Ms. Julia Helgeson
Staff Regulatory Affairs Specialist, Stryker Instruments
400 E. Milham Avenue
Kalamazoo, MI 49001

Re: K152641
Trade/Device Name: Pi Drive Plus Motor, Extender
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL, DZJ, HBE
Dated: October 23, 2015
Received: October 26, 2015

Dear Ms. Helgeson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152641

Device Name
Stryker Pi Drive Plus Motor

Indications for Use *(Describe)*
The Stryker Pi Drive Plus Motor is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental, ENT (ear, nose and throat), Neuro, Spine and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact Details			
510(k) Owner	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, Michigan 49001 US		
FDA Establishment Registration Number	1811755		
Submitted By	Deval Patel, MS, RAC Senior Regulatory Affairs Specialist Ph: +1-269-389-5671 Fax: +1-269-389-5412 E-mail: Deval.Patel@Stryker.com		
Date Submitted	September 14, 2015		
Device Name			
Trade Name	Stryker® Pi Drive Plus Motor		
Common Name	Ear, Nose, and Throat Electric or Pneumatic Surgical Drill		
Classification	Class II		
Primary Classification Name	*Drill, Surgical, Ent (Electric or Pneumatic) including Handpiece* (21 CFR 874.4250, Product code ERL)		
Secondary Classification Name	*Driver, Wire, and Bone Drill, Manual* (21 CFR 872.4120, Product code DZJ)		
	Drills, Burs, Trephines & Accessories (Simple, Powered) (21 CFR 882.4310, Product code HBE)		
Legally Marketed Predicate Device			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
Predicate			
K141935	ERL, HBE, DZJ	Stryker® S2 Drill	Stryker Instruments

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Indication for Use

The Stryker Pi Drive Plus Motor is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Device Description

The Stryker Pi Drive Plus Motor is a non-sterile, reusable, electric powered (40V DC) motor that rotates cutting accessories up to speeds of 75,000 RPM. It is powered by the CORE console. The cable of the Pi Drive Plus Motor is integrated into the proximal end and connects directly to the CORE console. The subject drill speed is controlled by a foot switch (connected to the CORE Console) or a removable handswitch which triggers a sensor within the handpiece. A variety of attachments and accessories can be used in conjunction with the drill. The motor (drill), cable, handswitch and footswitch are considered non-patient contacting device.

The Extender is an optional direct drive accessory that attaches to the distal end of the drill and transmits torque from the drill to various attachments. The Extender provides an option to add length to the drill, based on the user preference. The Extender is delivered non-sterile, re-usable, constructed of stainless steel material and is considered a non-patient contacting device.

Performance Data (Non-Clinical Tests)

The results of the performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker Pi Drive Plus Motor and Extender is sufficient for their intended use and support a determination of substantial equivalence to the predicate device.

Summary of Performance Testing

The following verification tests were performed on the subject device to demonstrate that device meets performance requirements under its indication for use conditions.

- Reliability Testing- Motor (Drill), Handswitch Functional

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Range Testing and Extender

- Graphic Legibility Testing for Motor (Drill) and Extender
- Temperature Testing

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject device are sufficient for their intended use, indications for use and support a determination of the substantial equivalence.

Clinical Tests No clinical testing was deemed necessary for this 510(k).

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Table 6-1: *Summary of Predicate Comparison*

DESCRIPTION	***STRYKER S2 DRILL [PREDICATE] K141935***	**STRYKER® Pi DRIVE PLUS MOTOR *[SUBJECT]***
Indication for Use	The Stryker S 2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The Stryker Pi Drive Plus Motor is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Classification of Device	Class II	Class II
Primary Product Code	ERL *Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece*	ERL *Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece*
Primary Regulation	*21 CFR 878.4250* *Ear, nose and throat electric or pneumatic surgical drill*	*21 CFR 878.4250* *Ear, nose and throat electric or pneumatic surgical drill*
Condition of Use	Reusable	Reusable
Type of Use	Prescription Use Only	Prescription Use Only
Patient Population	General	General
Contraindications	None known	None known
Mode of Action	Rotary (transmits Torque)	Rotary (transmits Torque)
Power source	40 V DC Electric Motor connected via cable to CORE console	40 V DC Electric Motor connected via cable to CORE console
Diameter of Motor	17mm	17mm
Length of the Motor	123.5mm	109mm

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Table 6-1: *Summary of Predicate Comparison (Continued)*

DESCRIPTION	***STRYKER S2 DRILL [PREDICATE] K141935***	**STRYKER® Pi DRIVE PLUS MOTOR *[SUBJECT]***
Weight of the Motor	313g	403g
Maximum Speed	75,000 rpm	75,000 rpm
Accessories	• CORE Console • Attachments • Cutting accessories • Irrigation Clips	• CORE Console • Attachments • Cutting accessories • Irrigation Clips • Extender
Means of Speed Control	Footswitch	Handswitch or Footswitch
Grip Design	Smooth	Knurled
Cutting Accessories Retention Method by Drill	Burs: Mechanical Lock	Burs: Mechanical Lock
	Routers: Routers are not utilized with the S2 Drill	Routers: Spring Collar Mechanism
Attachment Retention Method by Drill	*Attachments (Except Footed Attachment):* Mechanical Lock	*Attachments (Except Footed Attachment):* Friction
	Footed Attachment: Footed Attachments are not utilized with the S2 Drill	*Footed Attachment:* Mechanical Lock
Housing Material of Drill	Stainless Steel and Aluminum	Stainless Steel and Aluminum
Cable Material	Silicone	Silicone and Slick Sil LSR coating
Method of Sterilization	Moist Heat (Steam)	Moist Heat (Steam)
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}
Cleaning Method	Manual and Mechanical (automated)	Manual and Mechanical (automated)
Packaging	Packaged in a sealed retention insert	Packaged in a sealed retention insert

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Conclusion/Substantial Equivalence Rationale	The Stryker Pi Drive Plus Motor is substantially equivalent in indications for use, intended use, technological characteristics, safety and effectiveness to the previously cleared Stryker S2 Drill. The subject device has the same operating principle, functional characteristics and applications as the predicate device. The modifications introduced raise no new issues of safety and effectiveness. Therefore, the subject device is substantially equivalent to the existing predicate device.